DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 20 1986

Re: Novafil (4,224,946)
Docket No. 85E-0550
Novafil (4,246,904)
Docket No. 85E-0551

Mr. Charles E. Van Horn
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

#25

Dear Mr. Van Horn:

This is in regard to the applications for patent extension for U.S. Patents No. 4,224,946 and 4,246,904, filed in the alternative by American Cyanimid Co. under 35 U.S.C. § 156. The medical device claimed by the patents is Novafil, premarket approval application (PMA) number 84-0041.

In the February 10, 1986 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). That notice provided that on or before August 9, 1986, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice has expired and FDA has received no such petition. FDA therefore considers its determination of the regulatory review period for Novafil final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: John J. Hagan
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